

**REMARKS/ARGUMENTS**

Claims 1-5 and 20-26 remain in this application. Entry of the foregoing and favorable reconsideration and examination of the above-application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, and in light of the following remarks is respectfully requested.

Applicants respectfully submit that the current amendments are solely of a clarifying nature, and do not constitute narrowing amendments. No new matter has been added by these amendments. Claims 16 to 19 have been withdrawn without prejudice or disclaimer to the subject matter therein or in response to the final rejection of these claims as being drawn to a non-elected invention. Applicants reserve their rights to pursue the subject matter of the cancelled claims in a continuation application or divisional application

**Claim Objections**

Claims 1, 22, 24, 26 and 27 have been objected to because of a number of informalities. Claim 27 has been cancelled. The current amendments to claims 1, 22, 24 and 26 incorporate the language courteously suggested by the Examiner. Applicants respectfully submit that these amendments render the objections moot.

**Rejections under 35 U.S.C. § 112**

The Office Action states that claims 1-5 and 20-27 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabling any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Specifically, the Office Action states that—while being enabling for a cotton plant grown from the cotton deposited at the ATCC under Accession number PTA-3343 comprising elite event EE-GH1, and progeny of said cotton plant comprising elite event EE-GH1—the specification

allegedly does not reasonably provide enablement for any cotton plant that comprises elite event EE-GH1 not produced from the deposited cotton plant or for a method of making any cotton plant that comprises elite event EE-GH1 or any transgenic cotton plant, seed, cell or tissue comprising a transgene integrated into the chromosomal DNA region of elite event EE-GH1. The Office Action further alleges that—given the little guidance provided by Applicants, the nature of the invention, and the unpredictability of the art—producing elite events in plant would have required undue trial and error experimentation by one of skill in the art at the time of Applicants' invention to reproduce elite event EE-GH1 in another cotton plant, without resorting to the cotton plant deposited at the ATTC. According to the Office Action, it is particularly pertinent that the prior art teaches that it is difficult to target transgenes to specific loci in the chromosomes of a plant and thereby create a heteroallelic recombination target, and that such methods cannot be applied to flowering plants such as cotton in the instant case.

Claim 27 has been cancelled. In as far as the objection still applies to the amended claims, Applicants respectfully traverse.

Applicants note that the Examiner has rejected claims 1-5 and 20-27 as allegedly including claims toward a method of making any cotton plant that comprises elite event EE-GH1. However, Applicants also note that there are no such claims on record, nor have there been any claims on record directed specifically toward a method of producing plants which comprise elite event EE-GH1.

Applicants respectfully submit that claims 4, 5 and 20-22 are directed toward transgenic cotton plants, cells or tissue, grown or derived from the deposited seeds and that the Examiner has admitted such claims are considered to be enabled by the specification (*see* Paragraph 8 of the Office Action). Claims 21 and 22 have been phrased in accordance with the practice deemed allowable by

the U.S. Patent and Trademark Office for inbred plant lines (see attached claims from granted U.S. Patent Nos. 6,506,965 (claim 1), 6,617,500 (claim 1), and 6,624,345 (claim 1)).

Claim 20 has been rejected because, although it has been noted that Applicants have deposited the plants, there is no indication in the specification as to the public availability thereof. Accordingly, attached is a statement by the attorney of record stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent. Applicants respectfully submit that this attached statement renders the objection to claim 20 moot.

For at least the foregoing reasons, further in view of the Examiner's admissions, withdrawal of the rejections for at least claims 4, 5 and 20-22 is respectfully requested.

With regard to claims 1-3, Applicants note that these claims are *product* claims directed to transgenic cotton plants comprising elite event EE-GH1. As the Examiner will appreciate, and as indicated at least on page 19, last paragraph, the "elite event EE-GH1" can be introduced into any and all cotton plants or cultivars by classical breeding techniques, such as recurrent backcrossing. As such, Applicants respectfully submit that claims 1-3 are fully enabled over their entire scope.

According to the Office Action, a person skilled in the art would be unable to introduce nucleic acids by homologous recombination in plants, and particularly in flowering plants. However, Applicants respectfully submit that—since any and all cotton cultivar containing elite event EE-GH1 can be made by classical breeding with the publicly available (deposited) cultivar—it is legally irrelevant whether or not the application has enabled making cotton plants containing elite event EE-GH1 using targeted insertion via homologous recombination.

Indeed, as the Federal Circuit recently confirmed in *Amgen v. Hoechst Marion Roussel*: "*where the method is immaterial to the claim, the enablement inquiry simply does not require the*

*specification to describe technological developments concerning the method by which a patented composition is made that may arise after the patent application is filed.” Amgen*, 126 F. Supp. 2d at 160, 57 USPQ2d at 1515 (citing *Phillips Petroleum*, 865 F.2d at 1251, 9 USPQ2d at 1465; *In re Koller*, 613 F.2d at 824-25, 204 USPQ at 707; *In re Hogan*, 559 F.2d at 606, 194 USPQ at 538) (emphasis added); *see also id.* at 161, 57 USPQ2d at 1516 (discussing the ‘080 patent), 163-64, 57 USPQ2d at 1518 (discussing the ‘349 patent). Thus, the specification’s failure to disclose the later-developed endogenous activation technology cannot invalidate the patent. *Id.* at 160, 57 USPQ2d at 1516. Further, “*the law makes clear that the specification need teach only one mode of making and using a claimed composition.”* *Id.* at 160, 57 USPQ2d at 1515 (citing *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361, 47 USPQ2d 1705, 1719 (Fed. Cir. 1998)) (emphasis added); *see also Engel Indus. Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991) and *Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1308, 59 USPQ2d 1238, 1244 (Fed. Cir. 2001).

As correctly indicated by the Examiner, claims 23-26 are claims drawn to cotton plants comprising a transgene integrated into the chromosomal DNA region of the elite event EE-GH1 and processes for obtaining same. However, these claims are not limited to “reproducing elite event EE-GH1 in another cotton plant,” nor do they require such a reproduction. The Office Action asserts that reproducing elite event EE-GH1 would also include the absence of the deleted target DNA that came about with the transformation event. However, Applicants respectfully submit that this assertion is without merit. All that is required by these claims is that the transgene is inserted into the insertion site where the transgene is inserted in elite event EE-GH1.

Furthermore, the fact that the art allegedly teaches that homologous recombination in cotton plants is irreproducible—if feasible at all in flowering plants—is irrelevant. Having at hand the complete nucleotide sequence of the insertion region, it is well within the capacity of a person skilled

in the art to screen those plant cells or plants where the insertion of the transgene has occurred in the indicated region recited in these claims (e.g., by PCR amplification using two primers designed to amplify DNA with the nucleotide sequence of SEQ ID NO: 1). If insertion of the transgene occurred in this DNA region, the size of the amplified DNA fragment will be increased.

For at least the foregoing reasons, Applicants respectfully submit that claims 1-5 and 20-26 overcome the rejections under 35 U.S.C. § 112, first paragraph, and respectfully request the withdrawal of these rejections.

The Office Action states that claims 4, 5, 26 and 27 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Office Action states that claims 4 and 5 have been rejected as it is allegedly unclear if the claimed cotton plants, seeds, cells or tissues comprise elite event EE-GH1 or if Applicants intended to claim non-transgenic cotton plants. Applicants have amended the claims to include an express recitation that the claimed “plants, seeds, cells or tissues” should comprise elite event EE-GH1 in their genomes. Applicants respectfully submit that these amendments render the rejection moot.

The Office Action states that claim 26 has been rejected as allegedly being indefinite, because it is unclear if “the plant or cell or tissue” was directed to an untransformed plant or cell or tissue or if it was directed to the regenerated cotton plant comprising the transformed cotton cell or tissue. Applicants respectfully submit that the current amendment to claim 26—which amends the claim to specify that the plant, cell or tissue is transgenic—renders this rejection moot.

Claim 27 has been rejected as allegedly being indefinite because the claim reads on a transgenic cotton plant that does not comprise event EE-GH1. However, cancellation of claim 27 obviates the rejection.

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For at least the foregoing reasons, Applicants respectfully submit that claims 1-5 and 20-26 overcome the rejections under 35 U.S.C. § 112. As such, Applicants respectfully request removal of the rejections.

## **CONCLUSION**

Applicants note, with appreciation, that claims 1-5 and 20-27 have been found to be free of the prior art.

Applicants respectfully request entrance of the above specification and claim amendments.

In view of the above amendments and remarks, early notification of a favorable consideration is respectfully requested. Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below, to conduct an interview in an effort to expedite prosecution in connection with the present application. The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206.

Respectfully submitted,

Dated: October 7, 2003 By:

David H. Milligan  
Registration No. 42,893

HUNTON & WILLIAMS  
Intellectual Property Department  
1900 K Street, N.W.  
Suite 1200  
Washington, DC 20006-1109  
(202) 955-1500 (telephone)  
(202) 778-2201 (facsimile)